RADIO TEST REPORT

No. 1217630-4 ed. 1

EQUIPMENT UNDER TEST

Equipment:	Medical implant
Type / model:	Allure™ RF CRT-P, Model PM3222 Allure Quadra™ RF CRT-P, Model PM3242 See appendix A for a list of other model names with identical hardware
Manufacturer:	St. Jude Medical Inc
Tested by request of:	St. Jude Medical CRMD

SUMMARY

All selected test cases specified in this report comply with the requirements according to the following standards:

FCC 47 CFR Part 95 (2011)
IC RSS-243 Issue 3 (February 2010)

Industry Canada listed test facility No. IC 2042G-1

Date of issue: October 11, 2012

Tested by: Åke Carlson, Stefan Andersson — Approved by: Niklas Boström

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Revision History

Edition	Date	Description
1	**2012-10-11**	**First release**

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1. CLIENT INFORMATION

The EUT has been tested by request of

Company:	St. Jude Medical Inc 15900 Valley View Court Sylmar, CA 91342 USA
Name of contact:	Jorge Amely

2. EQUIPMENT UNDER TEST (EUT)

2.1 Identification of the EUT according to the manufacturer/client declaration

Equipment:	Medical implant
Type and serial number*:	Allure™ RF CRT-P, Model PM3222, S/N 8004680 Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665
Manufacturer:	St. Jude Medical
Rating/Supplying voltage:	Battery
External antenna connector:	No
Frequency range:	402-405 MHz
Number of channels:	10
Modulation characteristics:	2 FSK and 2 FSK fallback

*Emission bandwidth and Frequency error was measured on Allure™/ Allure Quadra™ RF CRT-P with wire access instead of battery and with SMA connector to RF antenna feed-through, S/N: 5009071.

2.2 Modifications during the test

No modifications have been made during the tests

3. TEST SPECIFICATIONS

3.1 Standards

FCC 47 CFR Part 95 (2011)
IC RSS-243, Issue 3 (February 2010)

Measurements methods according to ANSI C63.4-2003 - Methods of Measurements of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

3.2 Additions, deviations and exclusions from standards

The sidewall thickness of the torso simulator is 6.1 mm instead of 6.35 mm.

No other additions, deviations or exclusions have been made from standards.

3.3 Test setup and mode of operation

Test setup:
The EUT was suspended in a Plexiglas torso simulator comprised of a vertical cylinder 30 cm diameter by 79 cm height, with a sidewall thickness of 6,1 mm, bonded to a liquid-tight Plexiglas base. The cylinder was filled with fluid to 76 cm height. The simulator was constructed in accordance with FCC 95.639(a)(2)(i) and EN 301 839-1 A1.1.3. These are also references for the simulator fluid. The simulator fluid has been made and measured by Schmid & Partner Engineering AG to fulfill the standard, the measured values are σ = 0.94 s/m and ε' = 56.7 (target value: σ = 0.93 s/m and ε' = 57.2)

During testing the EUT was centered vertically in the Plexiglas cylinder and 6 cm from the sidewall. A plastic jig was used to position the EUT both vertically and horizontally in the cylinder. The electrodes were placed as a vertical coil of approximately 7 cm in diameter above the EUT.

Mode of operation:
Spurious emission and effective radiated power of the fundamental emission:
The EUT can transmit with 2FSK and 2FSK Fallback modulation. Spurious emission and effective radiated power of the fundamental emission was performed with 2FSK modulation which has the highest measured output power.

Frequency stability:
The EUT was transmitting without modulation.

Emission bandwidth and emission close to MICS band:
These tests were performed with 2FSK and 2FSK fallback modulation.

A fresh battery was used during radiated tests. During conducted tests the EUT was connected to a DC supply.

3.4 Operating environment

The tests in semi-anechoic chamber were performed under the following environmental conditions:

Air temperature:	20-25	°C
Relative humidity:	40-60	%

The conducted tests were performed under the following environmental conditions:

Normal condition:

Air temperature:	37	°C
Relative humidity:	40-60	%

Extreme condition:

Air temperature:	25-45	°C
Relative humidity:	40-60	%

4. TEST SUMMARY

The results in this report apply only to the sample tested.

FCC reference	IC reference	Test	Result
§95.635(d)	5.5	Unwanted radiation, Transmitter Unwanted Emissions	PASS
§95.639(f)	5.4	Maximum transmitter power, Transmitter Output Power	PASS
§95.633(e)	5.1	Emission Bandwidth	PASS
§95.628	5.3	Frequency error	PASS
§95.628(a)(b)	5.7	MICS operation and duty cycle requirement	NA*

* Only applicable for MICS controller/programmer

5. UNWANTED RADIATION AND MAXIMUM TRANSMITTER POWER

5.1 Measurement uncertainty

Radiated emission, field strength, 30 – 1 000 MHz: ± 4.6 dB
Radiated emission, field strength, 1 000 – 4 100 MHz: ± 6.2 dB

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997.
The measurement uncertainty is given with a confidence of 95%.

5.2 Test equipment

Equipment	Manufacturer	Type	Intertek No.
Test site: “BIG CHAMBER”			30300
Semi-anechoic shielded chamber, 9.9 x 19.8 x 6.8 m (W x L x H)			
Software:	Rohde & Schwarz	EMC32	-
Measurement receiver:	Rohde & Schwarz	ESU8	12866
Preamplifier:	Intertek	N/A	7992
Antenna, bilog:	Chase	6111	8578
Preamplifier:	Rohde & Schwarz	N/A	31246
Antenna, horn:	Rohde & Schwarz	HF 907	31245

5.3 Measurement set-up

Test site: Semi-anechoic shielded chamber (30 – 4100 MHz)

The radiated disturbance electric field intensity was measured in a semi-anechoic chamber at a distance of 3 m. The Plexiglas torso with the EUT was placed on a non-metallic table and the center of the torso and EUT was 1.5 m above the reference ground plane. The specified test mode was enabled. Test set-up photos are given below.

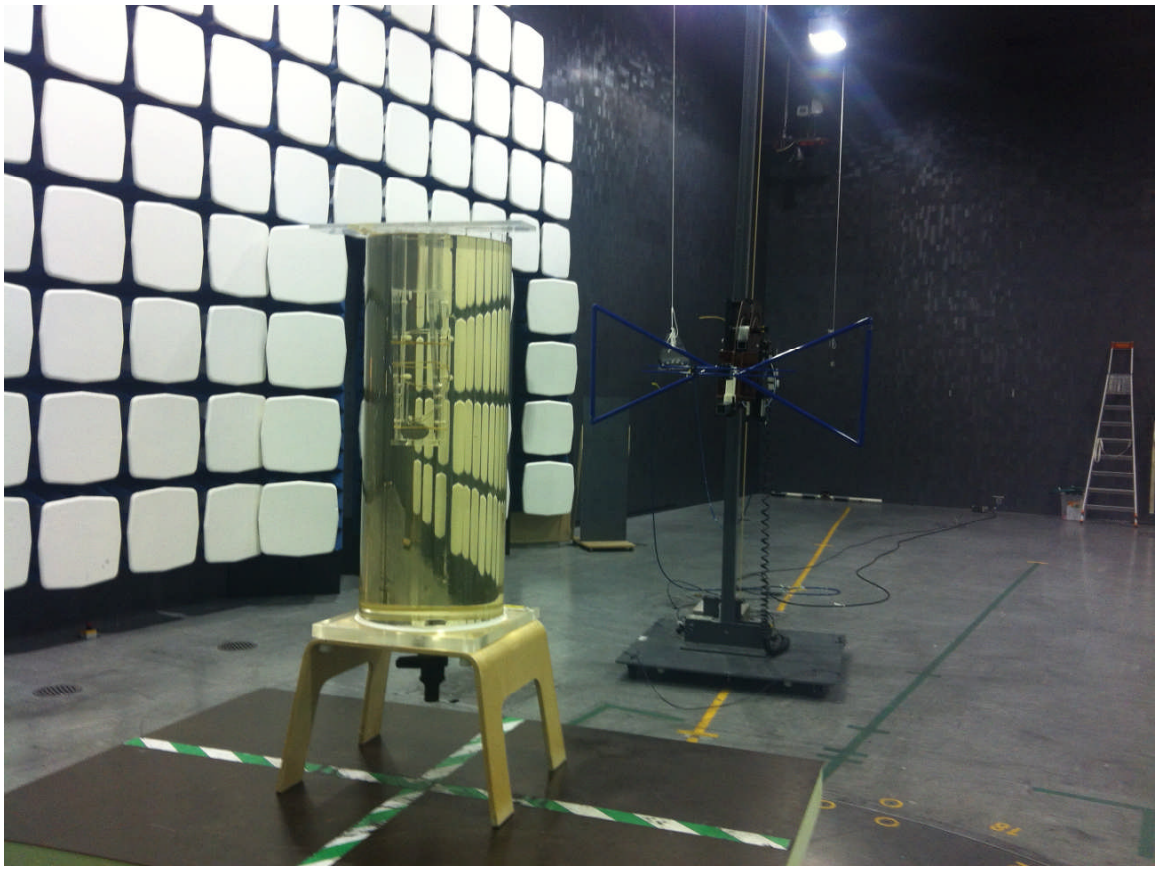
An overview sweep with peak detection of the electric field intensity was performed with the measurement receiver in max-hold and with the antenna placed 1.5 m, 2.5 m and 3.5 m above the floor. The polarization was horizontal and vertical. The measurements were repeated with the EUT rotated in 90-degree steps below 1 GHz and 45-degree steps above 1 GHz.

At the frequencies where high disturbance levels were found a search for max disturbance level was performed. With the EUT and antenna in the worst-case configuration new measurements with quasi-peak detector were carried out.

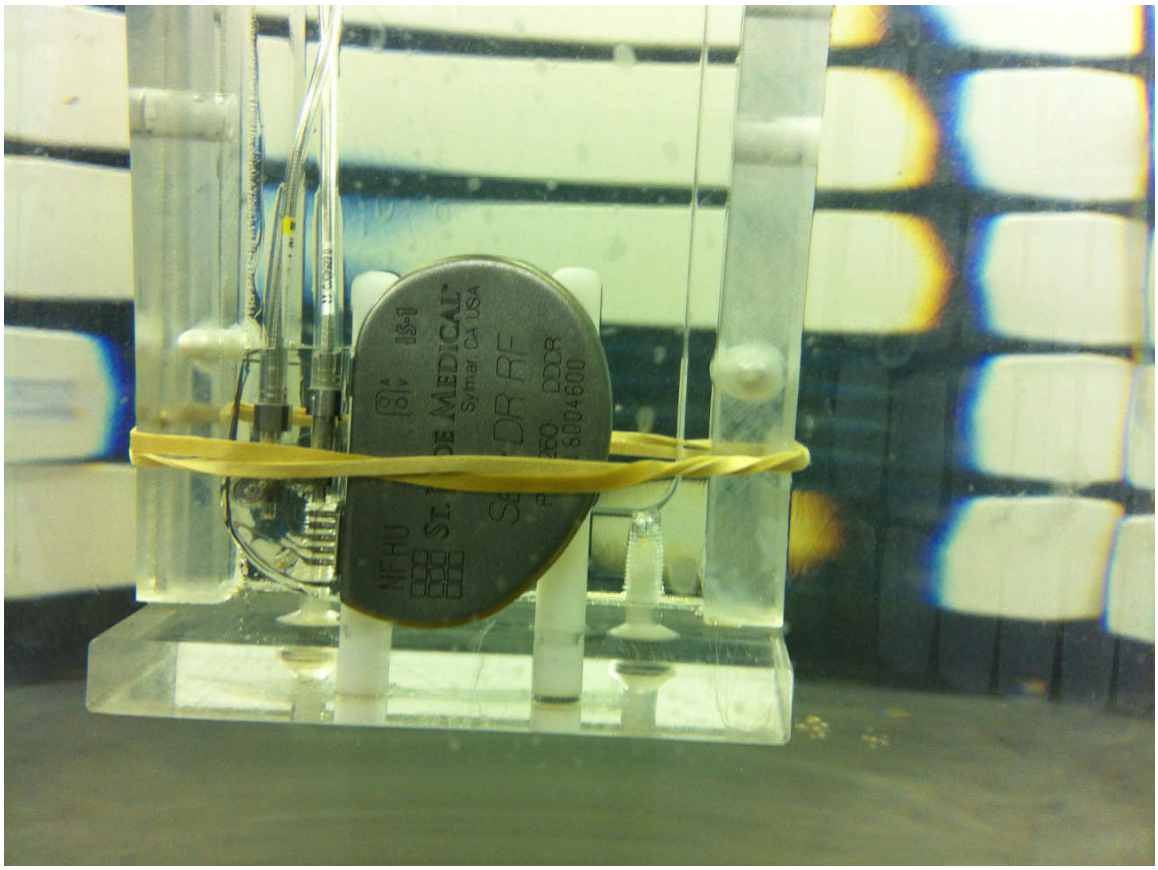
For maximum transmitter power measurement the turntable was turned 360 degrees and the antenna mast was moved from 1 m to 4 m to find the maximum power. The measurement was performed with both horizontal and vertical polarization.

Test set-up photos:

Test set-up, overview from EUT



Test set-up, EUT in Plexiglas cylinder

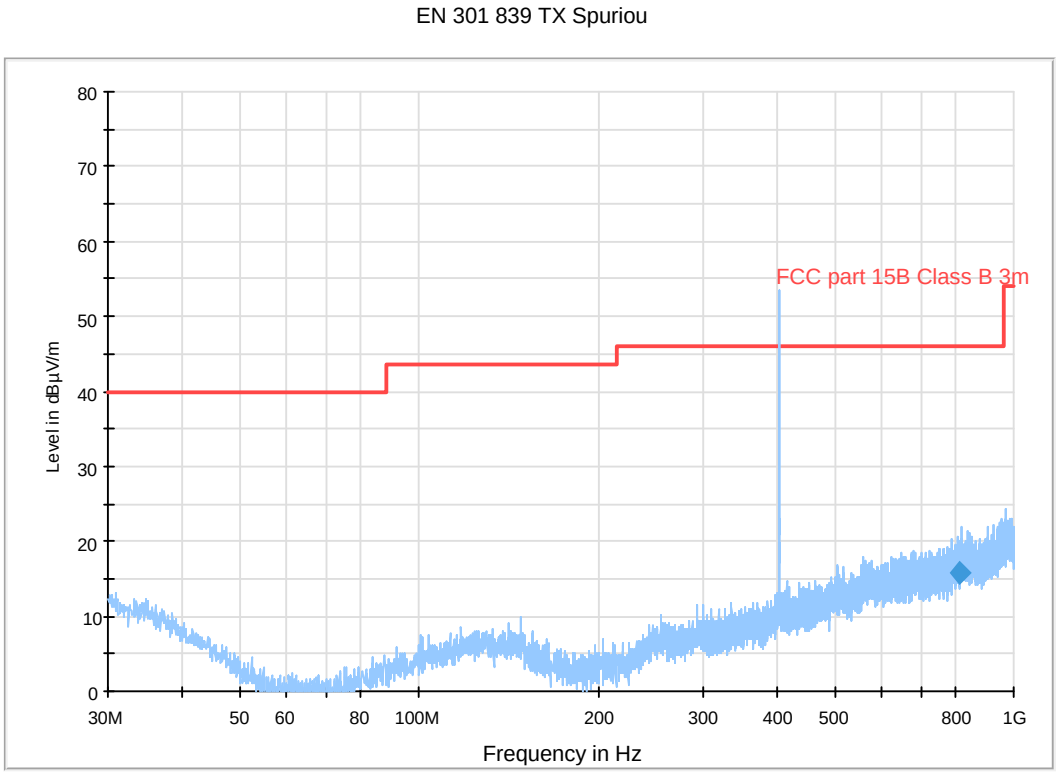


5.4 Test protocol, Unwanted radiation

Semi-anechoic shielded chamber

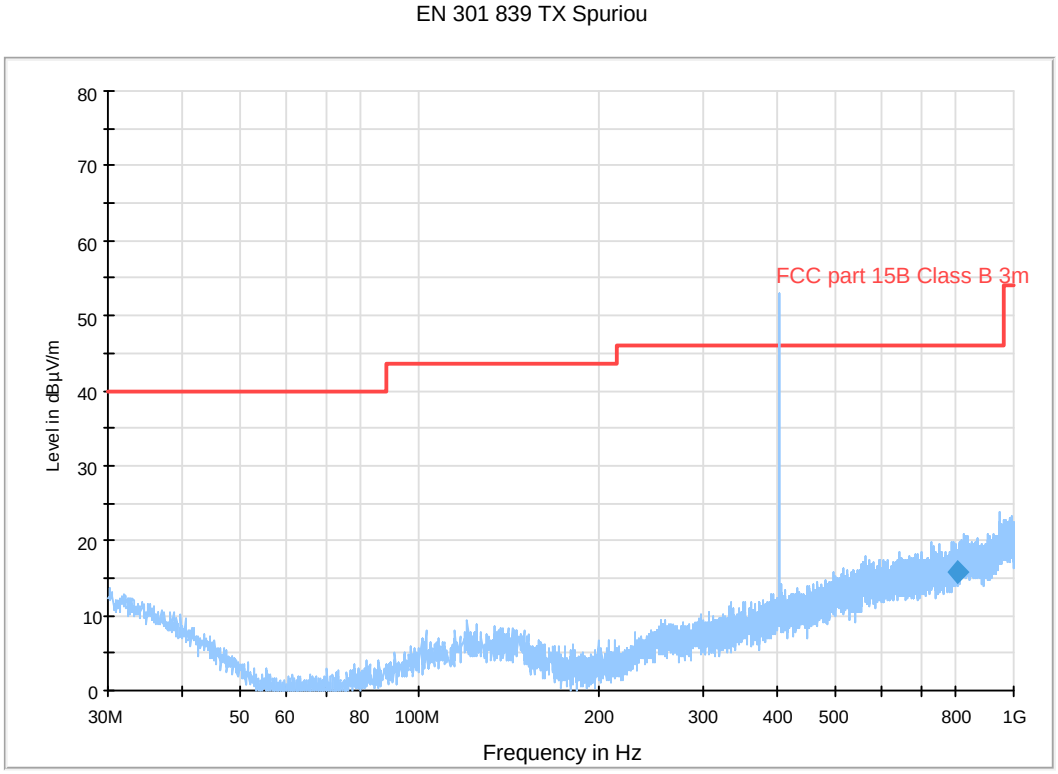
Date of test: 2012-09-17 and 2012-09-18

30 – 1000 MHz, max peak at a distance of 3 m, Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, vertical position



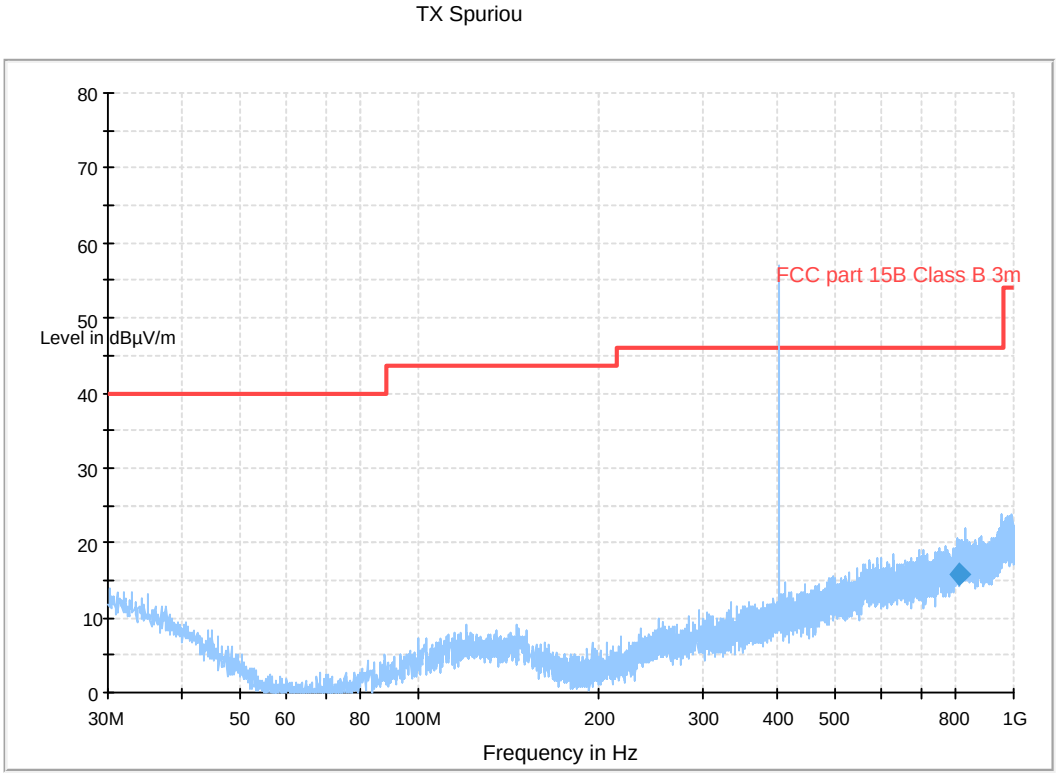
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

30 – 1000 MHz, max peak at a distance of 3 m, Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, horizontal position



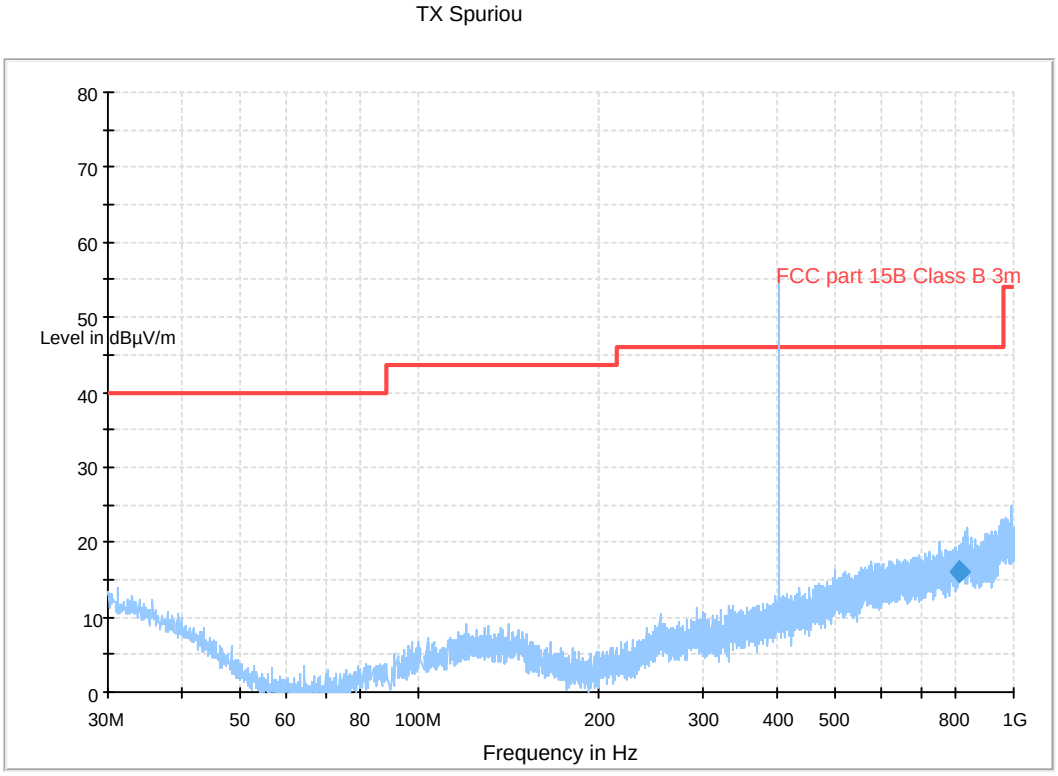
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

30 – 1000 MHz, max peak at a distance of 3 m, Allure™ RF CRT-P, Model PM3222, S/N 8004680, vertical
position



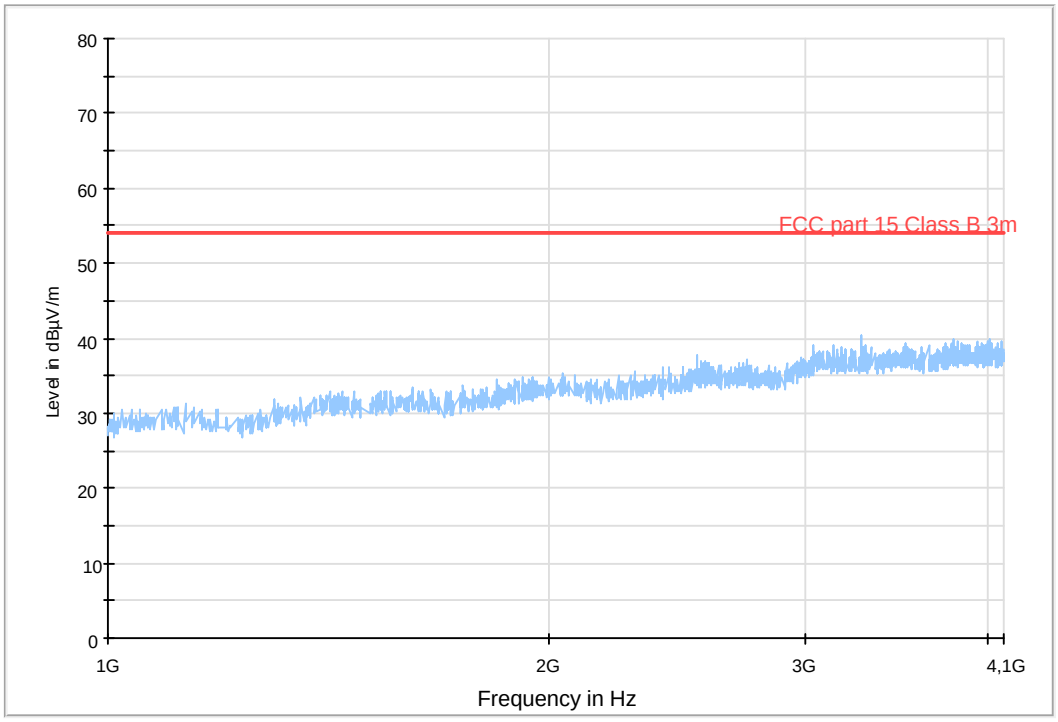
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

30 – 1000 MHz, max peak at a distance of 3 m, Allure™ RF CRT-P, Model PM3222, S/N 8004680, horizontal position



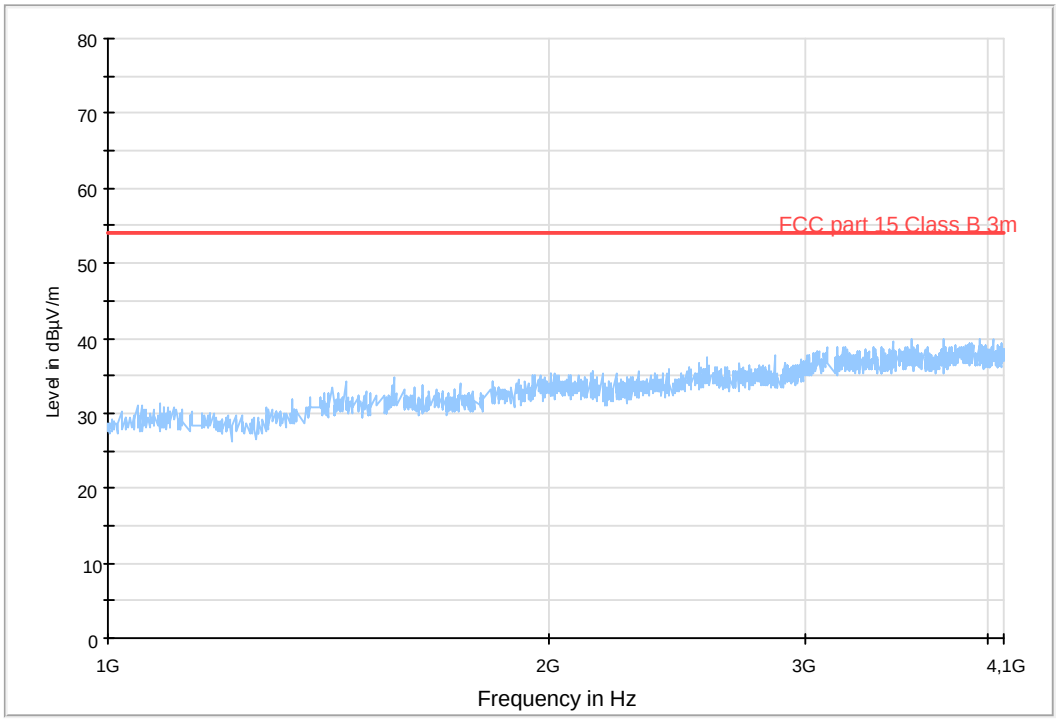
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

1000 – 4100 MHz, max peak at a distance of 3 m Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, vertical position



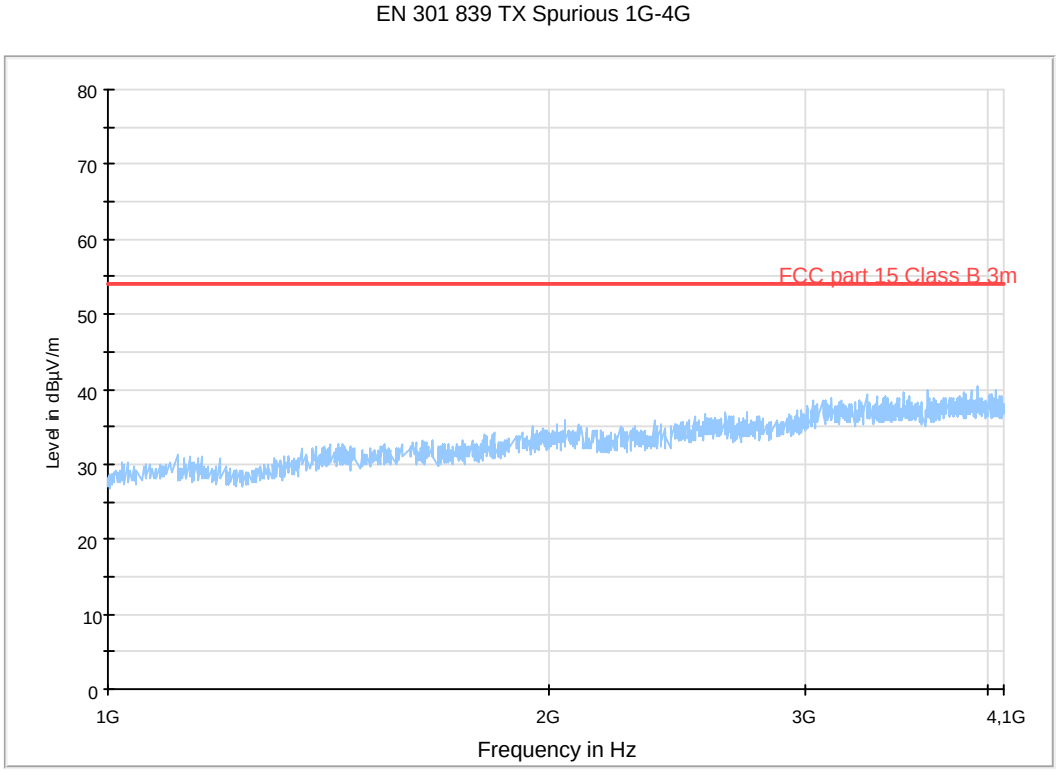
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

1000 – 4100 MHz, max peak at a distance of 3 m Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, horizontal position



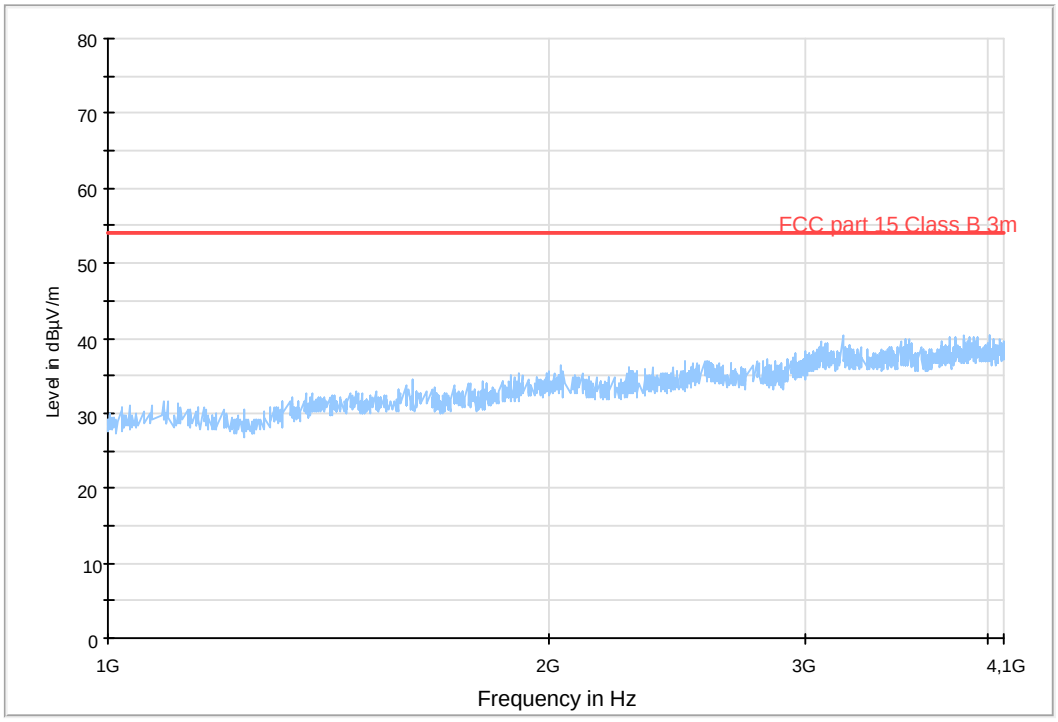
Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

1000 – 4100 MHz, max peak at a distance of 3 m Allure™ RF CRT-P, Model PM3222, S/N 8004680, vertical position



Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

1000 – 4100 MHz, max peak at a distance of 3 m Allure™ RF CRT-P, Model PM3222, S/N 8004680, horizontal position



Field strength of spurious emissions						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	-	-	-	-	-	Carrier
30 - 4000	-	-	-	-	-	No peaks above noise floor

Limit:

47-74 MHz 87,5-118 MHz 174-230 MHz 470-862 MHz		**Other frequencies below 1000 MHz**		**Frequencies above 1000 MHz**	
dBm (e.r.p)	**dBuV/m**	**dBm (e.r.p)**	**dBuV/m**	**dBm (e.r.p)**	**dBuV/m**
-54	49	-36	67	-30	73

Limit in e.r.p. has been recalculated to dBuV/m at 3 m measuring distance with reflecting floor.

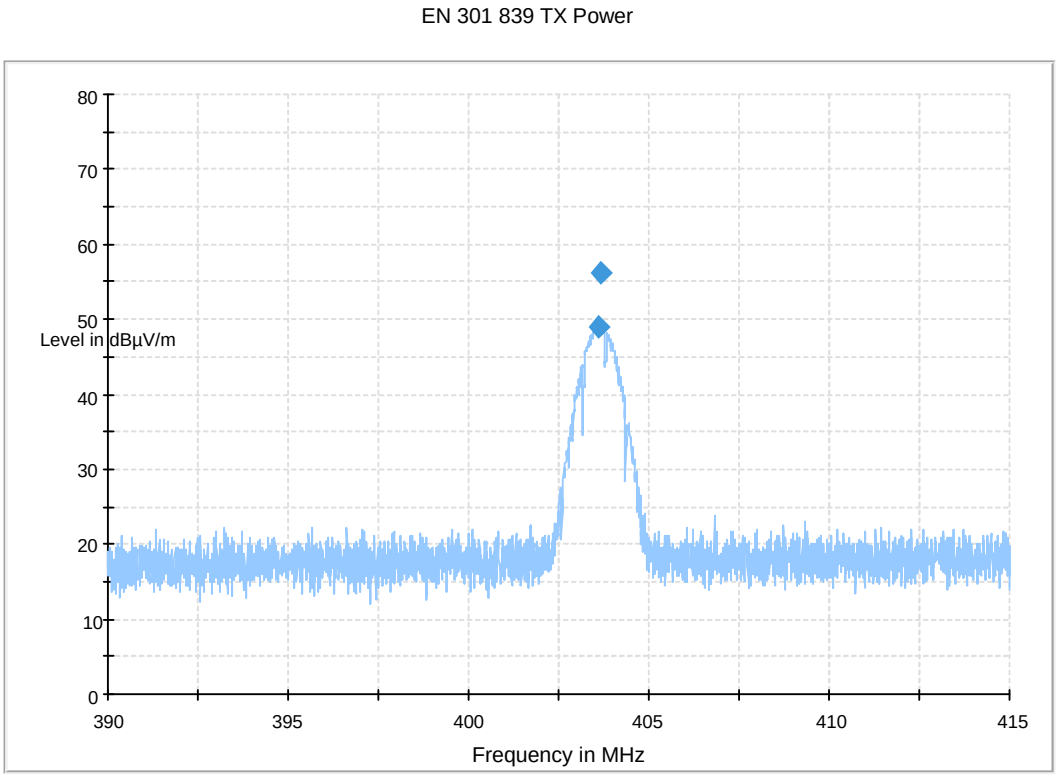
Fulfil requirements: YES

5.5 Test protocol, Maximum transmitter power

Semi-anechoic shielded chamber

Date of test: 2012-09-18 - 2012-09-19

Maximum transmitter power at a distance of 3 m, Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, vertical position



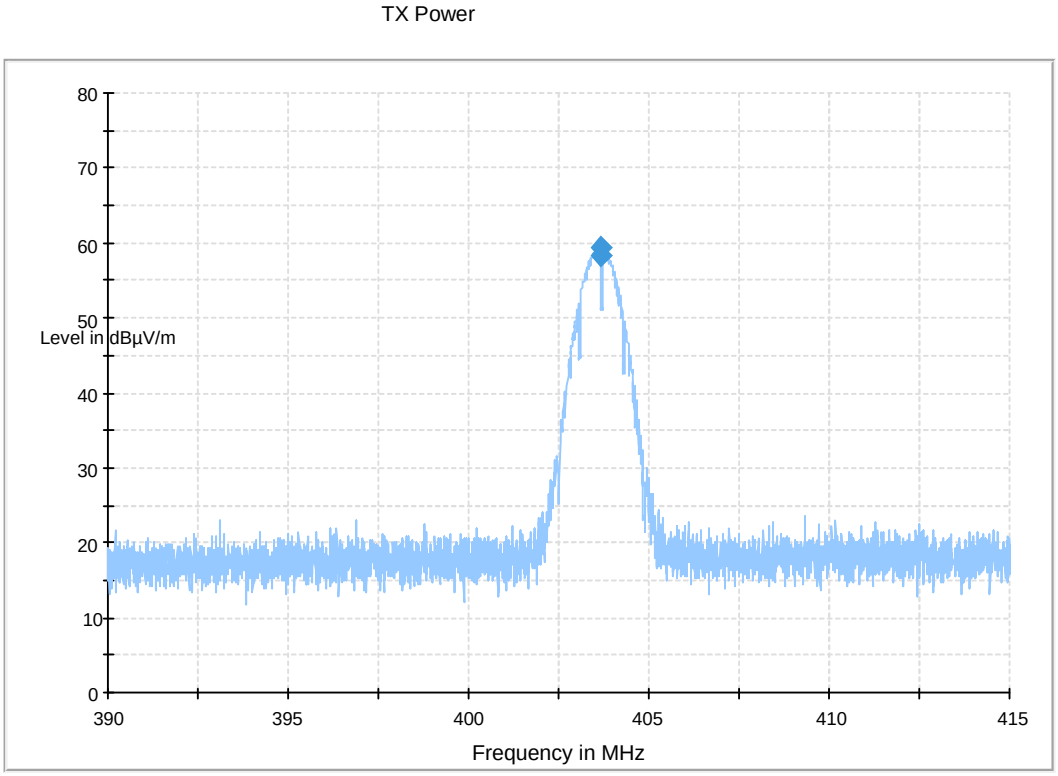
Maximum transmitting power						
Frequency	RBW	Measured level		Limit		Note
		Peak	QP/AV	Peak	QP/AV	
[MHz]	[kHz]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	[dB(µV/m)]	
403,650	1000	56.1	-	85.2	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).
P [µW] = 25*(10^(U[dB(µV/m)]/20)/18200)^2
P = 48,7 nW EIRP

According to FCC §15.503(k):
EIRP [dBm] = E [dBuV/m] - 95.2 (This equation is not counting with the reflecting floor in the chamber)
P = 195.0 nW EIRP

Maximum transmitter power at a distance of 3 m, Allure Quadra™ RF CRT-P, Model PM3242, S/N 8004665, horizontal position



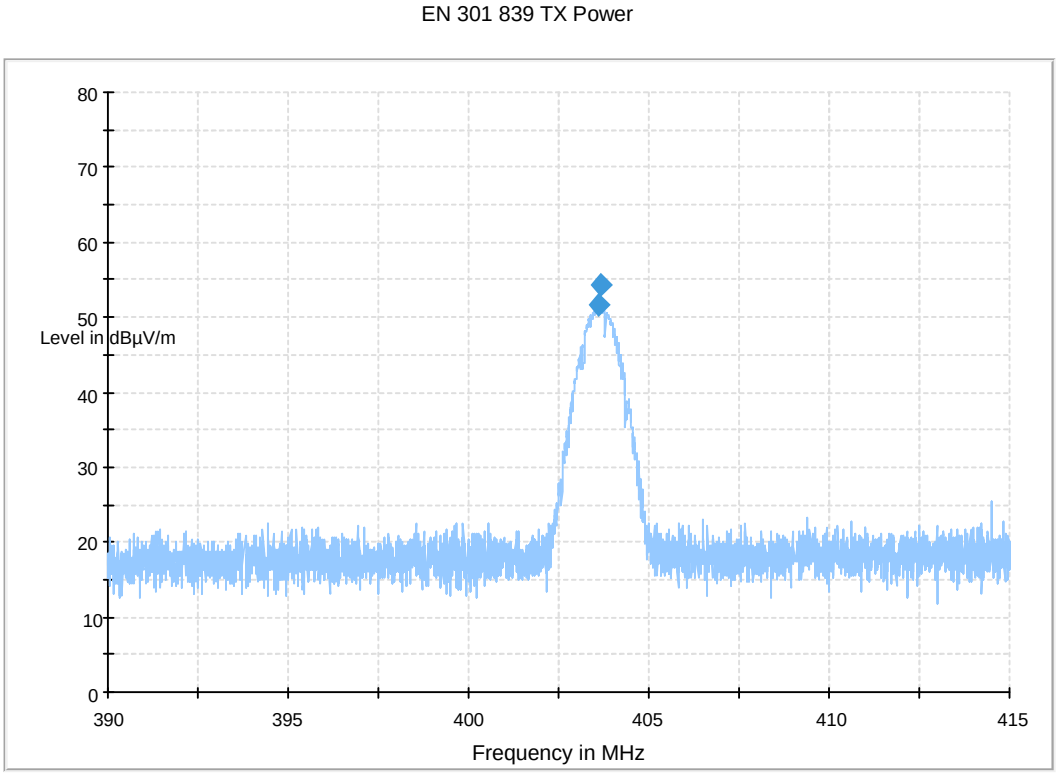
Maximum transmitting power						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	1000	53.2	-	85.2	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).
P [µW] = 25*(10^(U[dB(µV/m)]/20)/18200)^2
P = 51.0 nW EIRP

According to FCC §15.503(k):
EIRP [dBm] = E [dBuV/m] - 95.2 (This equation is not counting with the reflecting floor in the chamber)
P = 204.2 nW EIRP

Maximum transmitter power at a distance of 3 m, Allure™ RF CRT-P, Model PM3222, S/N 8004680, vertical position



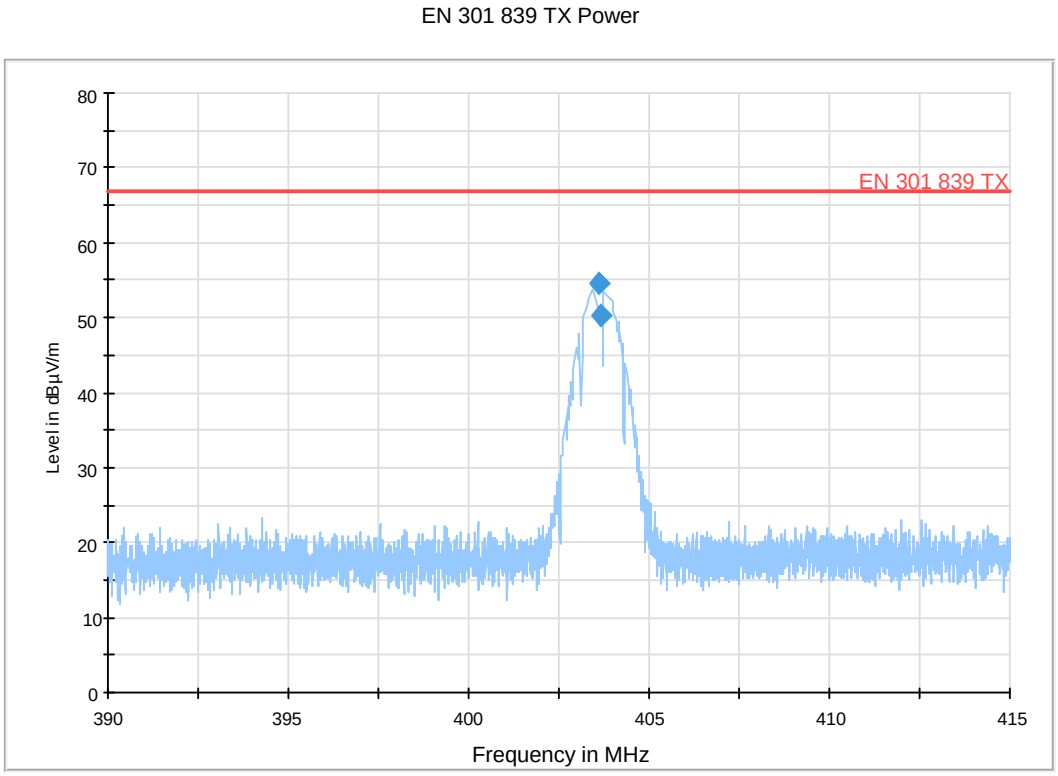
Maximum transmitting power						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	1000	54.2	-	85.2	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).
P [µW] = 25*(10^(U[dB(µV/m)]/20)/18200)^2
P = 54.7 nW EIRP

According to FCC §15.503(k):
EIRP [dBm] = E [dBuV/m] - 95.2 (This equation is not counting with the reflecting floor in the chamber)
P = 218.8 nW EIRP

Maximum transmitter power at a distance of 3 m, Allure™ RF CRT-P, Model PM3222, S/N 8004680, horizontal position



Maximum transmitting power						
Frequency [MHz]	RBW [kHz]	Measured level		Limit		Note
		Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	Peak [dB(µV/m)]	QP/AV [dB(µV/m)]	
403,650	1000	54.5	-	85.2	-	

Field strength to EIRP calculation:

According to FCC § 95.628(g)(3):
25 microwatts EIRP corresponds to 18.2 mV/m at 3 m measuring distance in a semi-anechoic chamber (reflecting floor).
P [µW] = 25*(10^(U[dB(µV/m)]/20)/18200)^2
P = 70.4 nW EIRP
According to FCC §15.503(k):
EIRP [dBm] = E [dBuV/m] - 95.2 (This equation is not counting with the reflecting floor in the chamber)
P = 281.8 nW EIRP

Example calculation, measured level:
Measured level [dBµV/m] = Analyzer reading [dBµV] + cable loss [dB] – preamplifier gain [dB] + antenna factor [1/m]
Limit: 25 µW e.i.r.p. correspond to 85.2 dB(µV/m) at 3 m antenna distance.
Fulfil requirements: YES

6. FREQUENCY ERROR

6.1 Measurement uncertainty

Frequency uncertainty at 400 MHz < 1 Hz

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997.
The measurement uncertainty is given with a confidence of 95%.

6.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Frequency counter:	Philips	PM6685R	5616

6.3 Test protocol

Date of test: 2012-09-19

Test conditions		Frequency (MHz)	Frequency drift (kHz)
		Middle channel	
T_{nom} 37°C	V_{nom} 2,80 V	403,6468	-
T_{min} 25°C	V_{min} 2,47 V	403,6476	+0.8
	V_{max} 2,80 V	403,6476	+0.8
T_{max} 45°C	V_{min} 2,47 V	403,6493	+2.5
	V_{max} 2,80 V	403,6493	+2.5

6.4 Limit

The frequency error shall not exceed ±100 ppm (40 kHz) under normal and extreme condition.

Fulfil requirements: **Yes**

7. EMISSION BANDWIDTH

7.1 Measurement uncertainty

Frequency uncertainty at 400 MHz < 1 Hz

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997.
The measurement uncertainty is given with a confidence of 95%.

7.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032

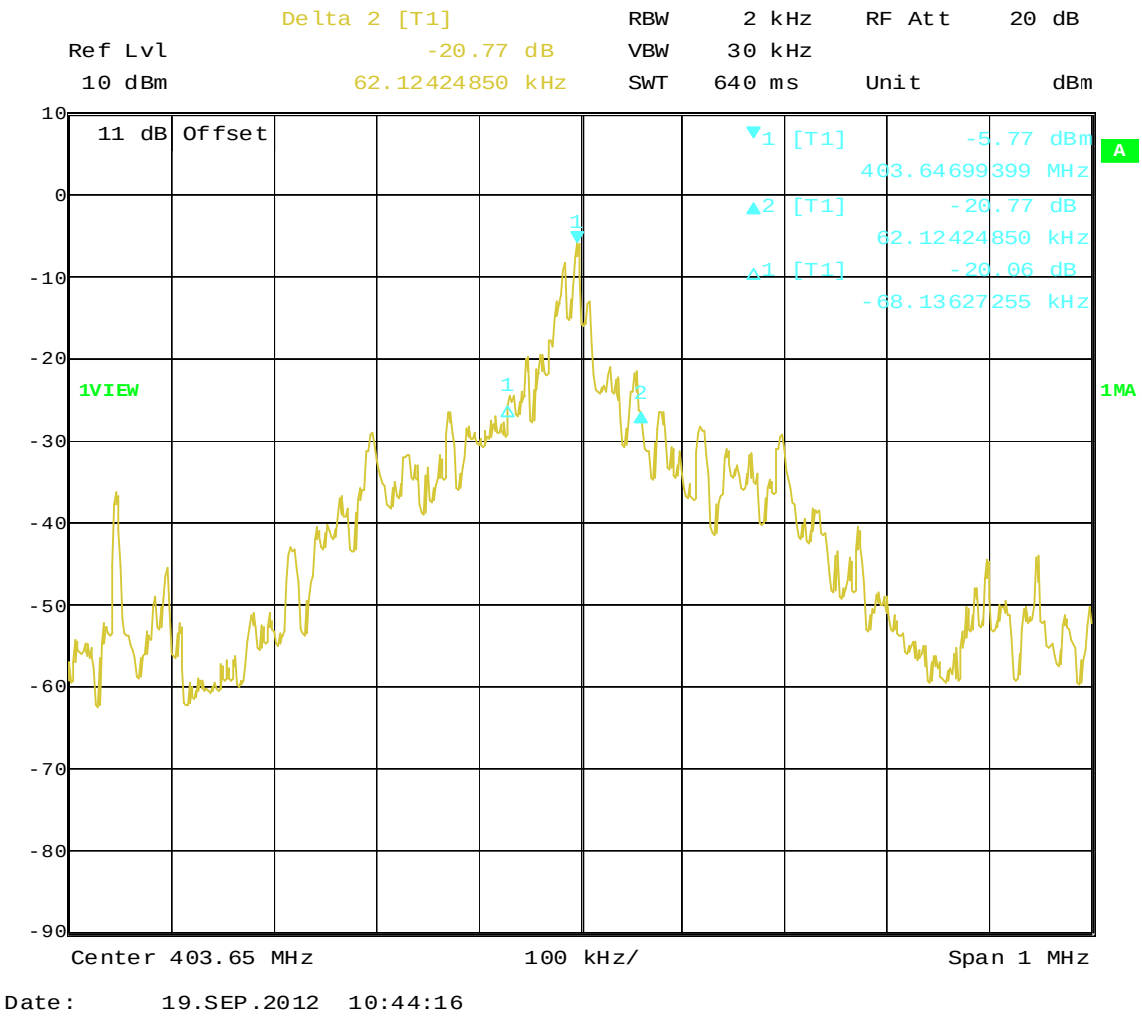
7.3 Test protocol

Date of test: 2011-09-19

20 dB Bandwidth:

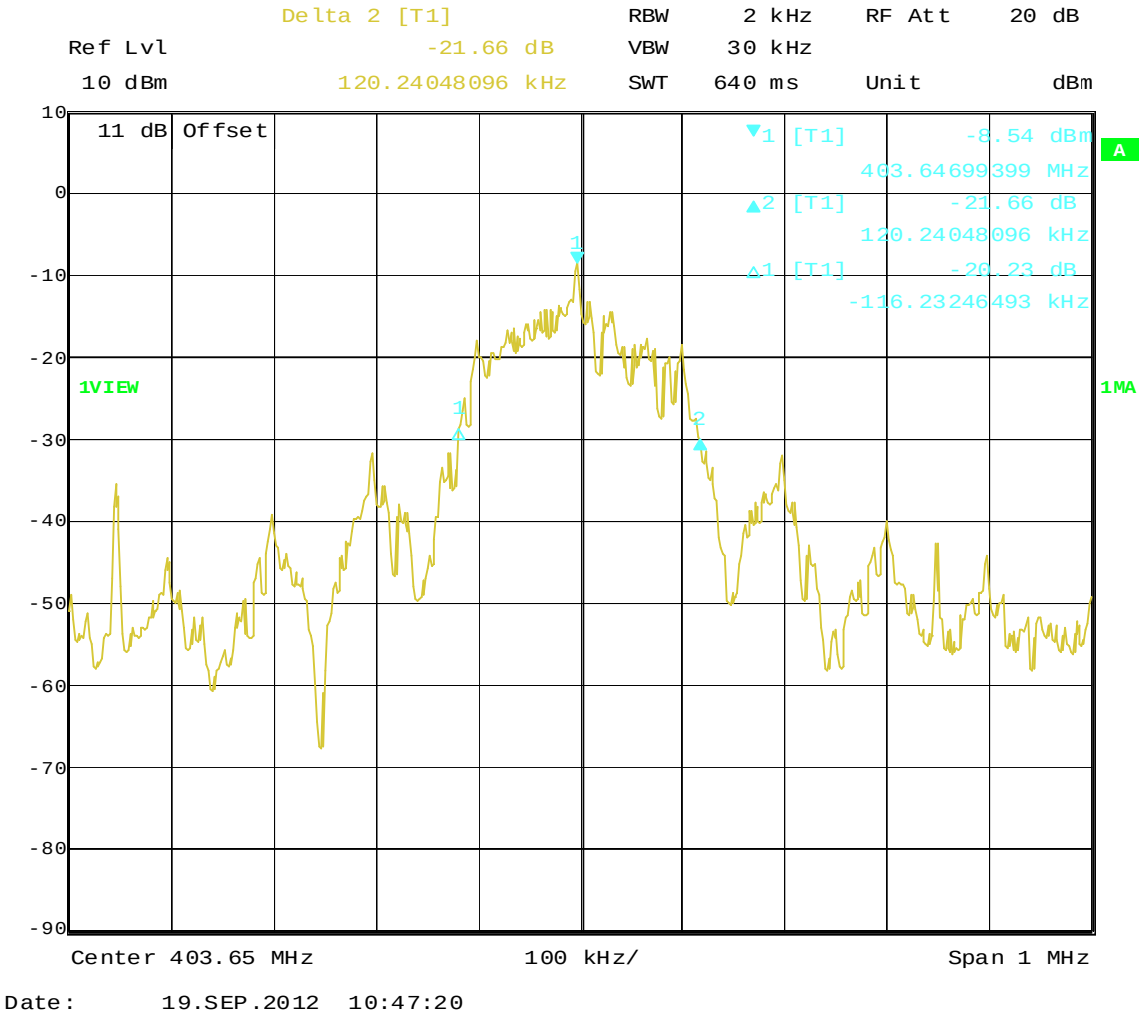
Middle Channel. 2FSK

Test conditions		Emission bandwidth
T_{nom} 37°C	V_{nom} 2.8 V	130.3 kHz



Middle Channel. 2FSK fallback

Test conditions		Emission bandwidth
T_{nom} 37°C	V_{nom} 2,8 V	236.5 kHz



7.4 Limits

The maximum permitted emission bandwidth shall be 300 kHz.

Fulfil requirements: **Yes**

8. UNWANTED EMISSION WITHIN MICS BAND

8.1 Measurement uncertainty

Measurement uncertainty: < 1 dB

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997.
The measurement uncertainty is given with a confidence of 95%.

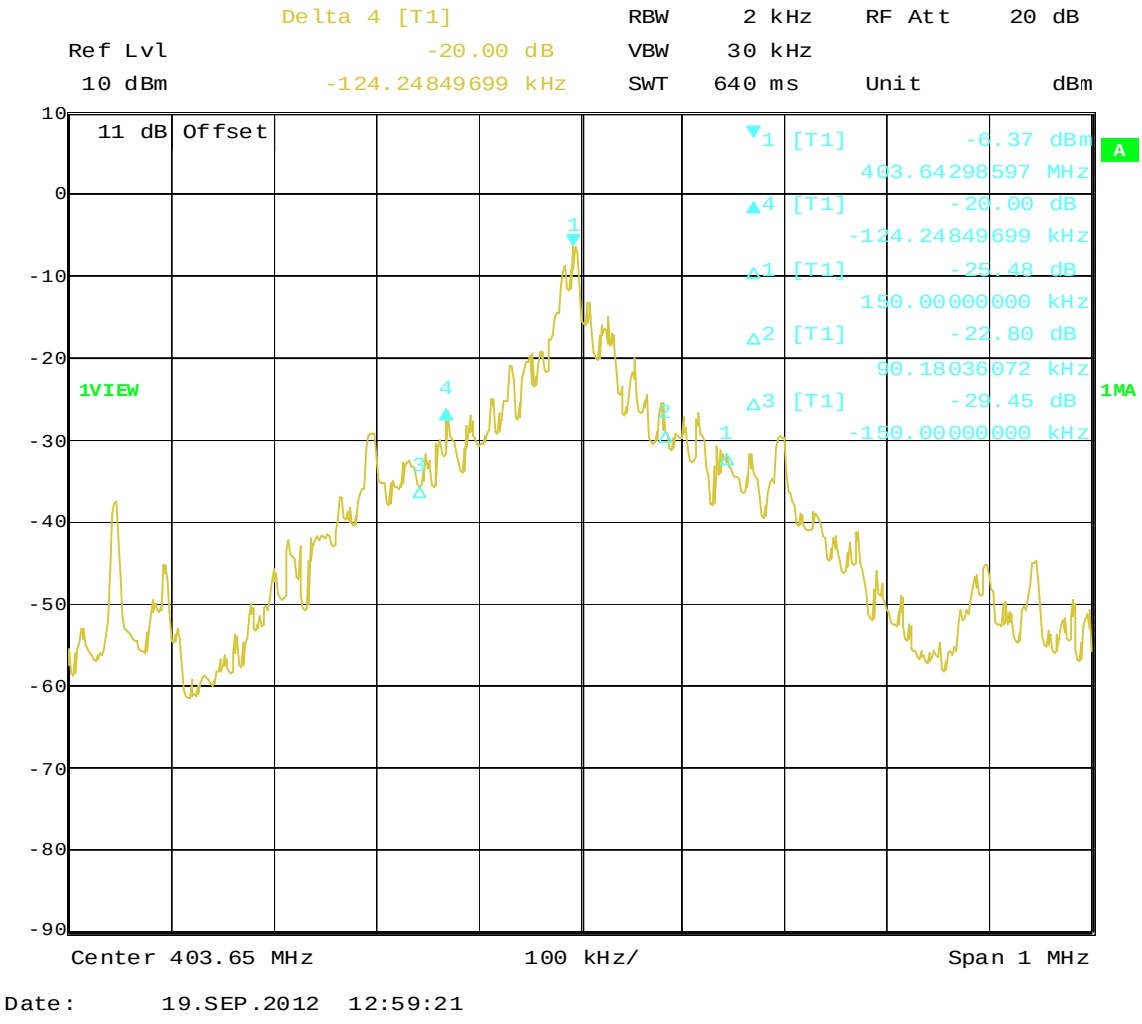
8.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032

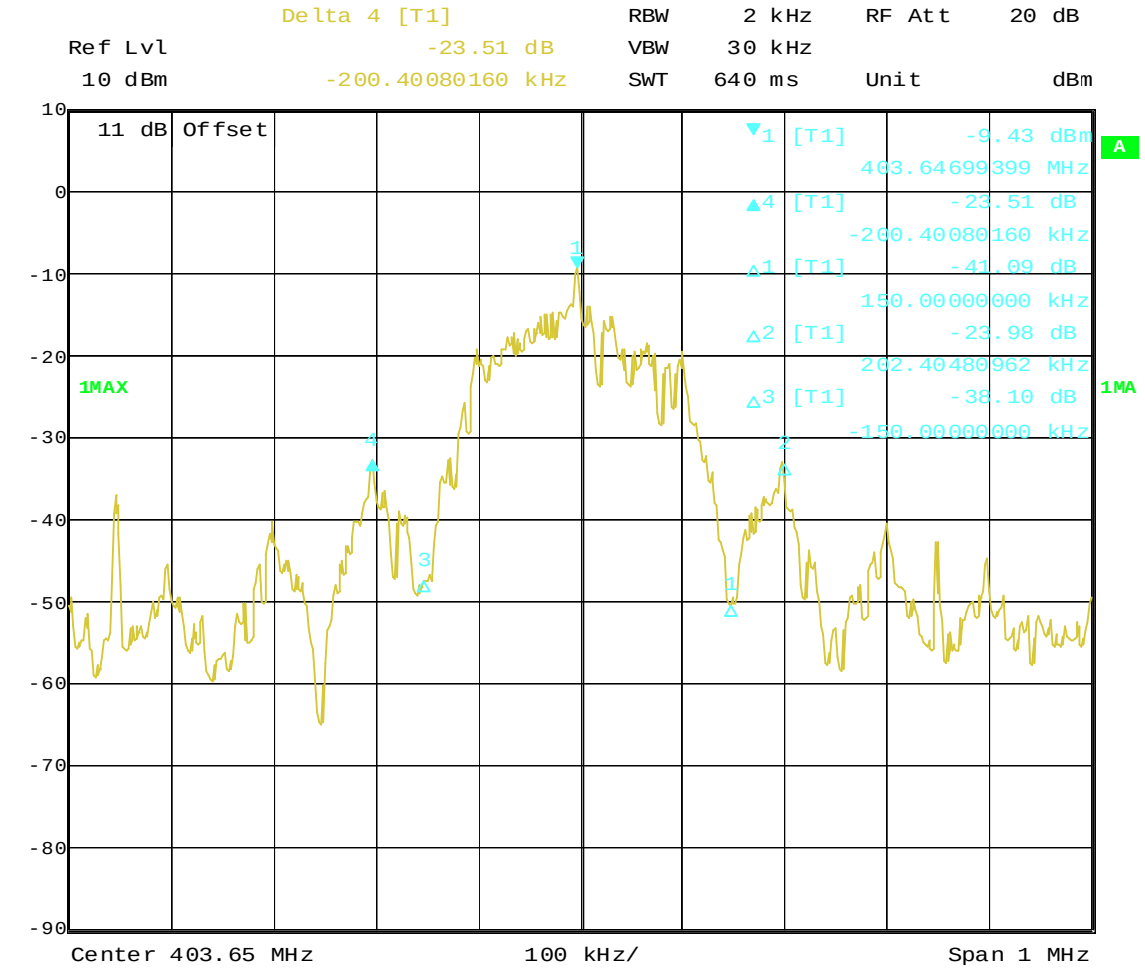
8.3 Test protocol

Date of test: 2012-09-19

Middle Channel. 2FSK



Middle Channel. 2FSK fallback



8.4 Limits

Emission within MICS band more than 150 kHz away from center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB.

Fulfil requirements: **Yes**

9. UNWANTED EMISSION CLOSE TO MICS BAND

9.1 Measurement uncertainty

Measurement uncertainty: < 1 dB

The measurement uncertainty describes the overall uncertainty of the given measured value during operation of the EUT.

Measurement uncertainty is calculated in accordance with EA-4/02-1997.
The measurement uncertainty is given with a confidence of 95%.

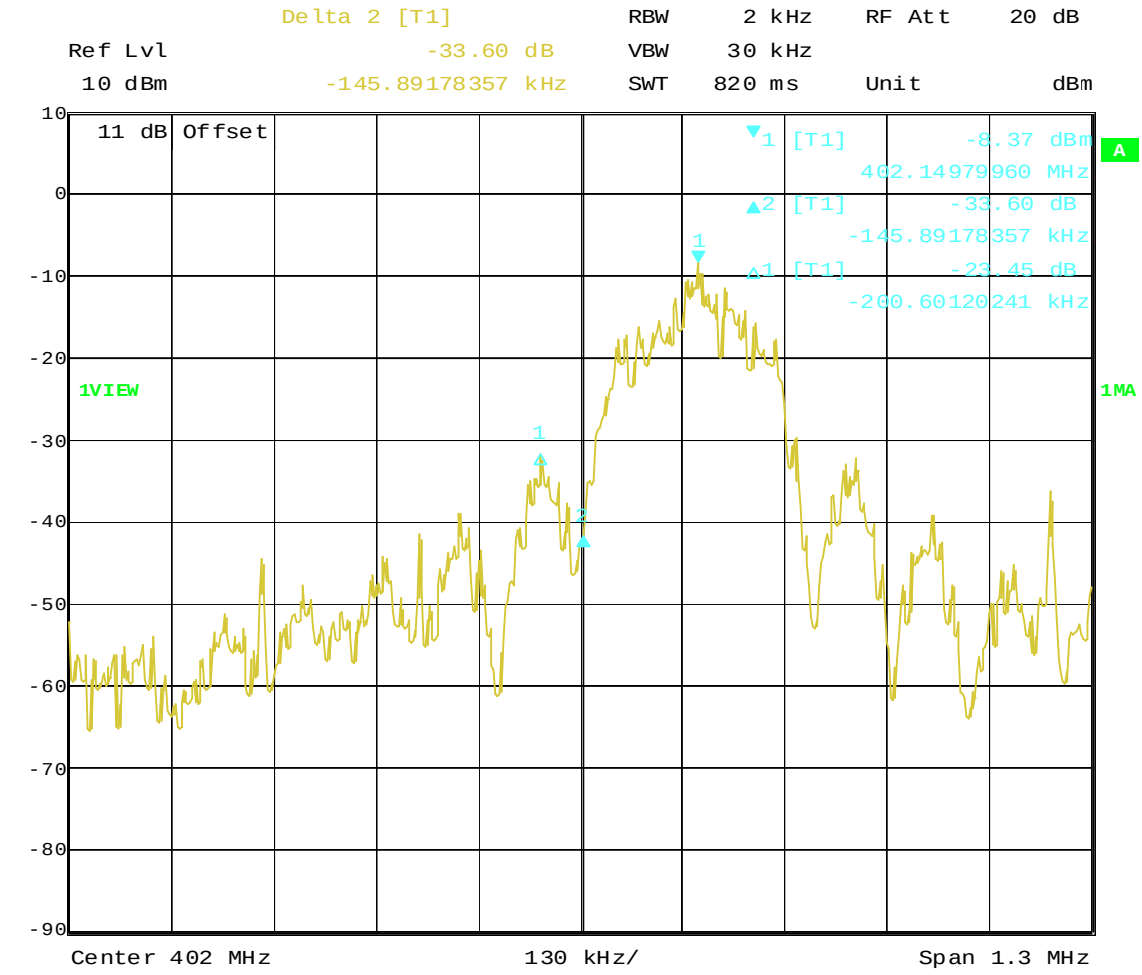
9.2 Test equipment

Equipment	Manufacturer	Type	SEMKO No.
Measurement receiver:	Rohde & Schwarz	FSIQ	12793
Rubidium oscillator	Datum	N/A	40032

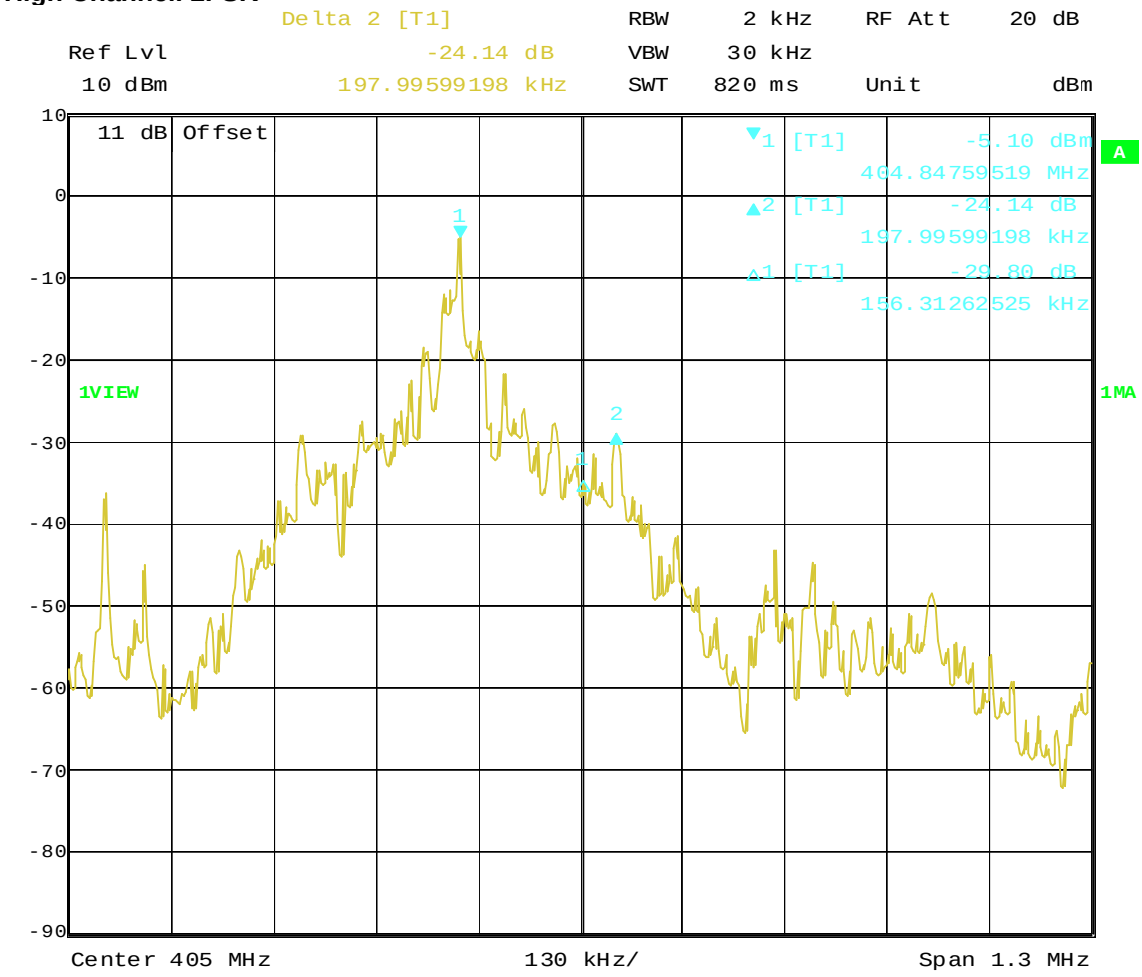
9.3 Test protocol

Date of test: 2012-09-19

Low Channel. 2FSK

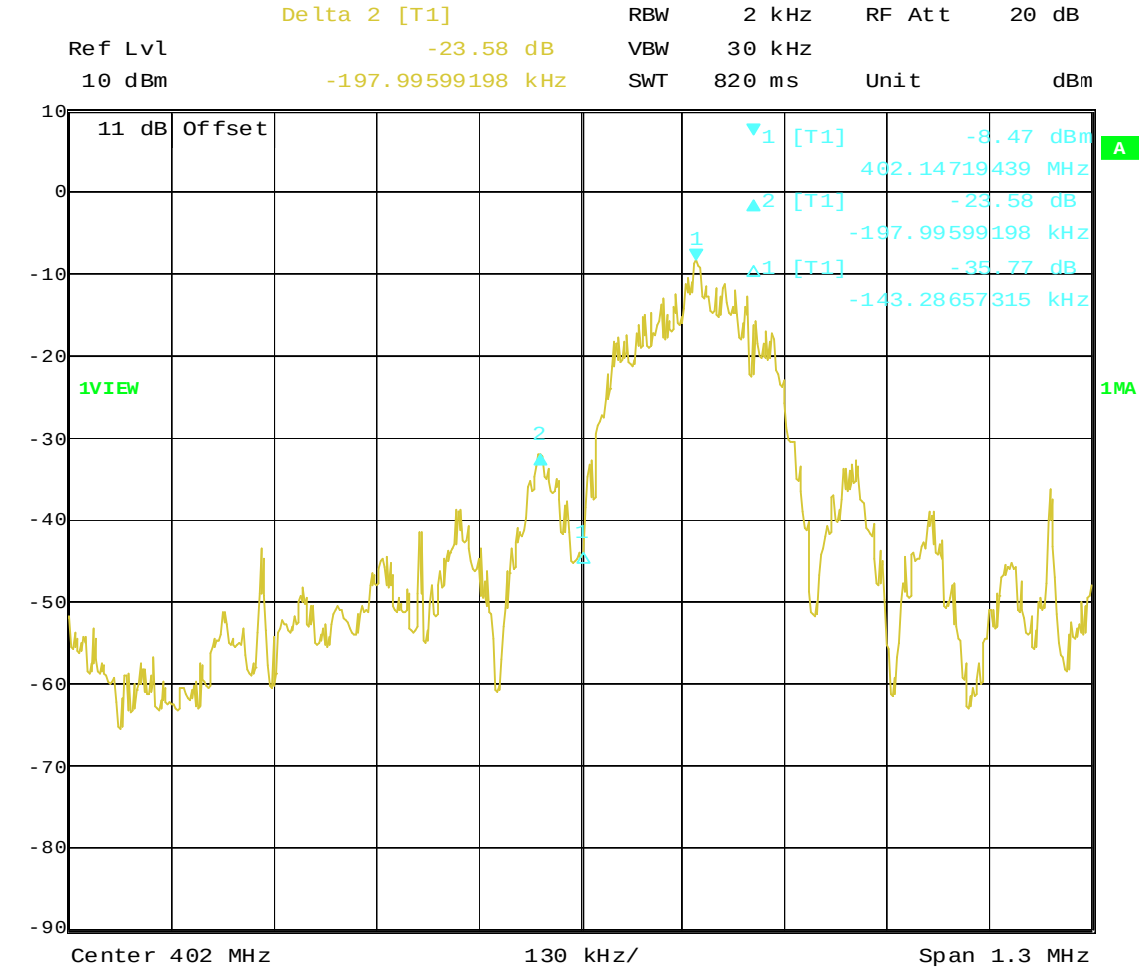


High Channel. 2FSK

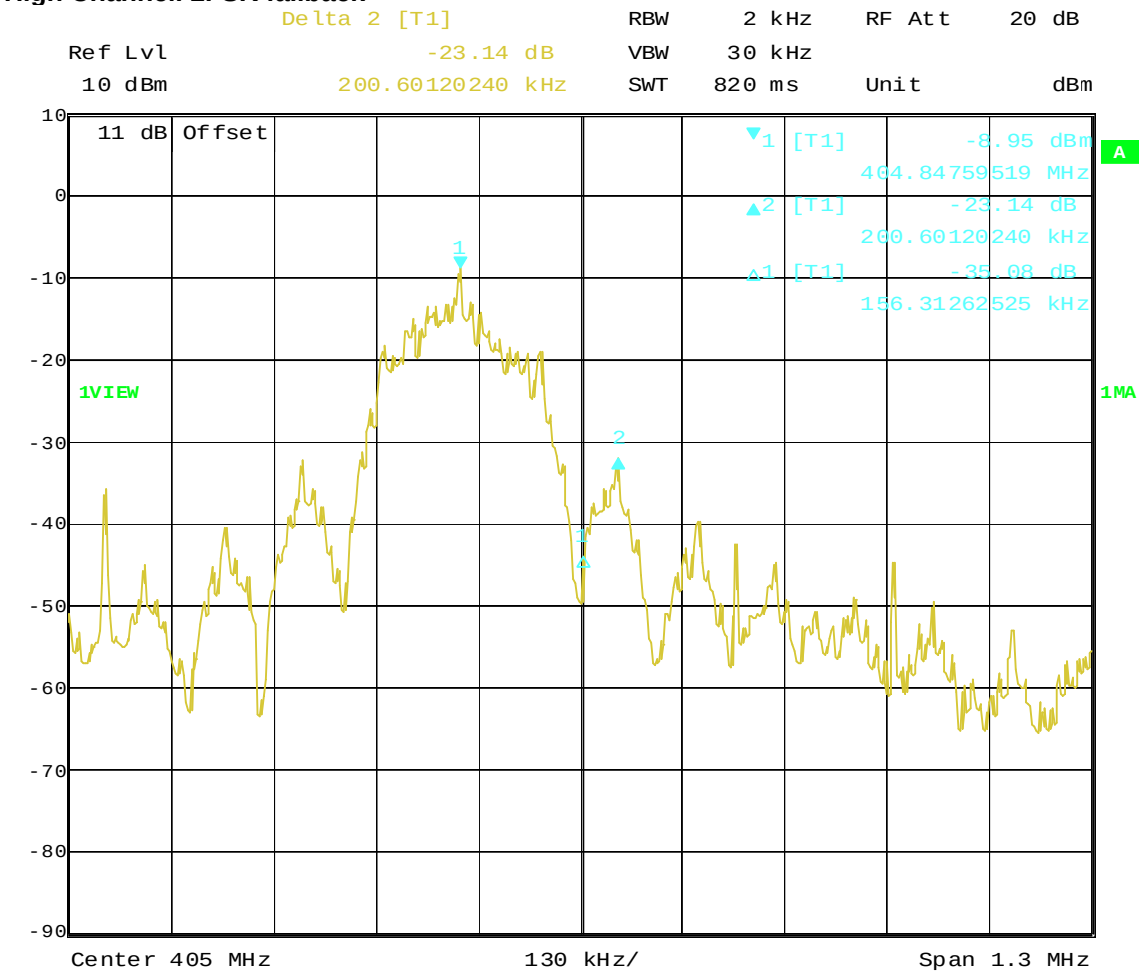


Date: 19.SEP.2012 13:28:54

Low Channel. 2FSK fallback



High Channel. 2FSK fallback



9.4 Limits

Emission 250 kHz or less that are above and below the MICS band will be attenuated below the maximum permitted output power by at least 20 dB.

Fulfil requirements: **Yes**

APPENDIX A

According to the manufacturer the hardware of the following models are identical with the tested samples:

Tested model:	**Hardware identical with:**
Allure™ RF CRT-P, Model PM3222	Allure™ RF CRT-P, Model PM3222
	Relieve™ RF CRT-P, Model PM3224
Allure Quadra™ RF CRT-P, Model PM3242	Allure Quadra™ RF CRT-P, Model PM3242
	Relieve Quadra™ RF CRT-P, Model PM3244